**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,<br><br>Defendants. | ) | Civil Action No. 98-80 (SLR)<br>(Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR)) |

**ACS'S RESPONSE TO MEDTRONIC'S**
**CITATION OF SUPPLEMENTAL AUTHORITY**

Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS") responds to Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively, "Medtronic") supplemental submission of the Federal Circuit's decision in *Cargill Inc. v. Canbra Foods, Ltd.*, Appeal No. 06-1265, 1302 (Fed. Cir. Feb. 14, 2007). For the reasons explained below, *Cargill* is readily distinguishable from the facts of this case.

In *Cargill*, the Federal Circuit held that the district court did not abuse its discretion in finding inequitable conduct where the patent applicant failed to disclose certain internal test data to the PTO during prosecution. The Federal Circuit summarized the relevant facts as follows:

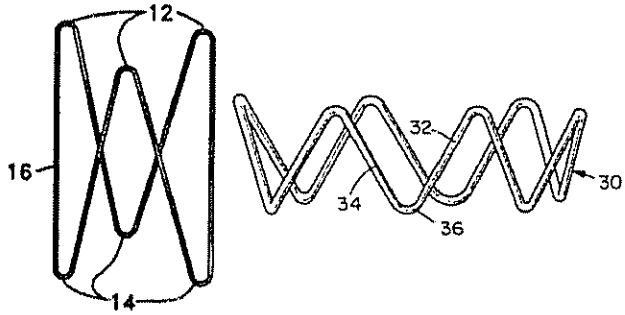
> [T]he applicant overcame the examiner's rejection by arguing that IMC 130 oil demonstrated an oxidative stability of 35 to 40 AOM hours, and that those stability values are strikingly superior to IMC 129 oil. However, the [unsubmitted] Report contains test data indicating that three samples of IMC 129 oil exhibited oxidative stabilities of 32, 35, and 32 AOM hours, which is a range similar to and, at one point, overlapping that of IMC 130. In addition, the

> [unsubmitted] Oven Data shows peroxide and para-anisidine values for IMC 129 that appear to be superior to those of IMC 130.

*Cargill*, slip op at 7-8. Based on those facts, the Federal Circuit agreed with the district court that the unsubmitted test data was material to patentability under the "reasonable examiner" standard and that the high degree of materiality, "coupled with evidence that the applicant should have known of that materiality," created a strong inference of an intent to deceive. *Id.* at 12.

*Cargill* is not applicable to the facts of this case, however. To begin with, there was apparently no dispute in *Cargill* that the applicants knew about the negative test data and failed to submit it. In contrast, here there is no evidence that the inventors—or anyone involved in the prosecution of the '154 patent—knowingly withheld the Boneau patent application.

Also, unlike the negative test data at issue in *Cargill*, the Boneau application was entirely cumulative to other references submitted during prosecution of the Lau '154 patent. For instance, the applicants submitted Lee '917 to the Patent and Trademark Office (the "PTO"), which discloses a plurality of "ring-like scaffold members" that are nearly identical in every relevant respect to the Boneau stent. Medtronic makes much of the fact that, in the pending reexamination of the '154 patent, the Examiner has rejected some claims based on a combination of Boneau '330 and Wolff '404. Medtronic fails to mention, however, that the Examiner concluded that "Boneau does *not* disclose a longitudinally flexible stent, comprising a plurality of interconnected cylindrical elements aligned along a common longitudinal axis . . ." (Office Action at ¶ 47, emphasis added.) Instead, the Examiner cited Boneau only for teaching a plurality of unconnected "cylindrical elements" with lengths




**Boneau '331 (left) and Lee '917 (right) both disclose stainless steel, balloon-expandable, zigzag structures for use in coronary arteries.**

less than their diameters. While ACS vigorously disagrees with that interpretation of Boneau[1], the fact remains that Lee '917 can be cited for the exact same teaching. Thus, in all relevant respects, Boneau is cumulative to Lee '917, which was submitted to the PTO during prosecution of the '154 patent.

Finally, unlike in *Cargill*, there is no evidence in this case of an intent to mislead the Examiner.[2] Quite the contrary, ACS submitted the Boneau reference in *three out of the four patents-in-suit*, bringing it to the Examiner's attention both in an interview and in a supplemental IDS. The Federal Circuit has held that such behavior "is not consistent with an intent to deceive." *Kimberly-Clark Corp. v. Proctor & Gamble Dist. Co* , 973 F.2d 911, 918 (Fed. Cir. 1992). Moreover, far from believing Boneau was material, Messrs. Lau, Khosravi, and Orth all testified that they believed Boneau's stent to be a very different design from Lau's. (D.I. 670 at 289; D.I. 671 at 394-95, 476-83.) That testimony is corroborated by the 1990 feasibility study, which literally ranked the two designs on opposite ends of the spectrum. (AX-268.)

In summary, the holding in *Cargill* has no applicability to this case because it was based on very different facts. For the reasons explained in ACS's post-trial brief, this Court should reject Medtronic's inequitable-conduct defense and enter an Order finding that the Lau '154, '167, '168, and '133 patents are not unenforceable due to inequitable conduct.

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[1] Boneau does not disclose "cylindrical elements" as construed by this Court, *i.e.*, radially expandable segments of a stent having a length less than their diameter, which are not, in and of themselves, stents. Instead, as this Court has ruled and as the Federal Circuit has affirmed, Boneau discloses functional, stand-alone stents. *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 182 Fed. Appx. 994, 997 (Fed. Cir. 2006) (unpublished)

[2] In *Cargill*, "[t]he district court found an intent to deceive based on several circumstantial factors: the repeated nature of the omission, the applicant's motive to conceal, and the high materiality of the undisclosed information." *Id.*, slip op. at 10.

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**CERTIFICATE OF SERVICE**

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